UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIONPHARMA INC., Plaintiff, v. CORERX, INC., Defendant.	Civil Action No. 21-10656-JGK

PLAINTIFF BIONPHARMA'S BRIEF IN OPPOSITION TO DEFENDANT CORERX'S MOTION (D.I. 82) FOR STAY OF INJUNCTION PENDING APPEAL

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INTRODUCTION

Plaintiff Bionpharma Inc. ("Bionpharma") respectfully submits this brief in opposition to the motion by defendant CoreRx, Inc ("CoreRx") to (i) stay the preliminary injunction pending appeal, and (ii) require Bionpharma to post an injunction bond.

The familiar four-factor standard applicable to CoreRx's motion for a stay requires, *inter alia*, a "strong showing" that the movant is likely to succeed on the merits. *Rodriguez v. DeBuono*, 175 F.3d 227, 234 (2d Cir. 1998). In an attempt to avoid the deferential "abuse of discretion" standard of appellate review applied to appeals from preliminary injunction rulings, *Zervos v. Verizon New York, Inc.*, 252 F.3d 163, 169 (2d Cir. 2001), CoreRx doubles down on its "patent policy" argument to try to create an issue of law. At oral argument of Bionpharma's motion for a preliminary injunction, the Court expressed skepticism about this theory and noted that CoreRx did not have a case that so held. Tr. 10:8-11:20. Even now, CoreRx still has no case holding, or even fairly suggesting, that an *allegation* of patent infringement preempts state-law remedies for breach of contract.

When viewed through the lens of the applicable standard of appellate review, the weakness of CoreRx's principal legal argument for reversal compels the conclusion that it cannot clear the likelihood-of-success hurdle. Nor, as explained below, does CoreRx satisfy the remaining parts of the four-factor standard, *i.e.*, "(2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Rodriguez*, 175 F.3d at 234.

For the first time now, CoreRx also seeks security for the preliminary injunction, despite its failure to even raise, much less carry its burden on, this issue during briefing and argument of Bionpharma's motion. Indeed, the proposed form of preliminary injunction that CoreRx *itself submitted* (D.I. 59) did not require security or even propose a briefing schedule to determine the

necessity for, or amount of, security. Even if submitting a form of order that does not provide for security does not reach the level of invited error, CoreRx's failure to have timely raised the issue is a waiver or forfeiture of any such entitlement. As to amount, the astronomical bond sought by CoreRx would (i) effectively negate the equitable relief to which Bionpharma has been found to be entitled, and (ii) reward CoreRx's sister company Azurity for its anticompetitive "settlement agreement" (D.I. 54-1) by re-establishing its monopoly position for Epaned.

Despite CoreRx's failure to establish its entitlement to security, Bionpharma is prepared to post an injunction bond of $200,000, which exceeds the transfer price of the roughly 18,000 bottles even using the higher per-bottle price sought by CoreRx in its proposed form of preliminary injunction. This is sufficient to protect CoreRx from any harm of nonpayment by Bionpharma, or in the unlikely event that CoreRx manufactures the necessary quantities to comply with the preliminary injunction but is relieved of its obligation to transfer them to Bionpharma by a Second Circuit reversal of the preliminary injunction.

Finally, the Court should deny as unnecessary—and potentially prejudicial to Bionpharma—CoreRx's request for a short stay in order to seek emergent relief from the Second Circuit. The deadline for CoreRx to deliver the first batch of product is March 4, 2022 (D.I. 79 ¶ 2). Between now and then, CoreRx must conduct the necessary production and quality control steps to meet that deadline. It should not be granted a stay that might open the door to an argument that its failure to comply with the preliminary injunction by delivering product on-time was excused by a temporary stay during which it was justified in stopping work.

I. CORERX IS NOT ENTITLED TO A STAY OF THE PRELIMINARY INJUNCTION PENDING APPEAL

In determining whether to issue a stay pending an appeal, courts in the Second Circuit consider four factors: "(1) whether the stay applicant has made a strong showing that he is likely

to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.'" *Rodriguez*, 175 F.3d at 227 (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)); *see also Hirschfeld v. Bd. of Elections in City of N.Y.*, 984 F.2d 35, 39 (2d Cir. 1993). The moving party bears the "heavy" burden of establishing that these factors weigh in its favor. *D'Amico Dry D.A.C. v. Primera Mar. (Hellas) Ltd.*, 431 F. Supp. 3d 317, 319 (S.D.N.Y. 2019).

CoreRx has not shown that any of the factors weigh in its favor.

A. CoreRx has not shown a strong likelihood of success on an appeal

The grant or denial of a preliminary injunction is reviewed on appeal for abuse of discretion. *Zervos*, 252 F.3d at 167. Accordingly, CoreRx's likelihood of success on appeal must be viewed through the lens of that difficult burden.

CoreRx's legal argument—that Bionpharma's state-law remedies for breach of contract are preempted by some vague concept of patent policy—is entirely without support in the cases. Taken to its logical end point, this remarkable proposition would jeopardize an enormous volume of commerce and innumerable commercial relationships in light of the ubiquity of patents and other federally recognized intellectual property rights. CoreRx's inability to find a single case on point in what would, under its theory, be a matter of hornbook contract law, speaks loudly to its absence. As expressed by Justice Holmes 100 years ago, "Upon this point a page of history is worth a volume of logic." *New York Trust Co. v. Eisner*, 256 U. S. 345, 349 (1921).

CoreRx's factual argument—that Bionpharma did not make an adequate showing of irreparable harm—founders on the shoals of the appellate standard of review. There is ample support in the cases that a supplier's refusal to furnish a unique product under a requirements contract may cause its counter-party irreparable harm sufficient to support injunctive relief, and

the facts found by the Court (i) were supported by the evidence, and (ii) fit comfortably into precedent.

1. The Supply Agreement is neither preempted by, nor illegal under, federal patent law

CoreRx's legal argument rests on an unproven assumption, *i.e.*, that enforcement of its obligations under the Supply Agreement "requir[es] CoreRx to violate the patent rights of third-party Azurity Pharmaceuticals, Inc." D.I. 83 at 5. It does no such thing. As the Court found, and which is not disputed, "[n]o court has yet held that Bionpharma's Product violates any federal patents." D.I. 50 at 18. Further, CoreRx did not even show in opposition to Bionpharma's motion for a preliminary injunction that an ultimate determination of patent infringement was *likely* if the patent cases against Bionpharma were to be litigated to judgment. To the contrary, the only indication to date on the merits of Azurity's potential patent claim—the Delaware court's denial of Azurity's motion for a preliminary injunction for lack of success on the merits (D.I. 11-1)—points in the *opposite* direction. Notably, Azurity did not appeal that denial, and its time to do so has expired.[1]

CoreRx's argument that a Supreme Court case abolishing the common-law doctrine of licensee estoppel, *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), also federalized contract law with respect to any agreement to manufacture or supply a product that might be alleged to infringe a patent is both legally and logically infirm. It is legally infirm because no case has so held in the

[1] The Court may take judicial notice of the docket of the Delaware case, Civil Action No. 21-01286, to see that Azurity's motion for a preliminary injunction was denied on November 10, 2021, and that Azurity has not filed a notice of appeal.

50-plus years since *Lear* was decided. It is logically infirm because the expressed purpose of the *Lear* decision was to remove state-law impediments that stood in the way of challenging patents.

If *Lear* can be generalized or extended, it points in the *wrong direction* for CoreRx. Contrary to CoreRx's argument, a *failure* to enforce the agreement would frustrate patent law and policy by providing an exclusionary remedy under state contract law that Azurity was unable to obtain under federal patent law. As the Court knows, Azurity already failed in its attempt to keep the Bionpharma product off the market using the available tools of patent law. It lost its first case following a bench trial in Delaware, *Silvergate Pharm., Inc. v. Bionpharma Inc.*, No. CV 18-1962-LPS, 2021 WL 1751148 (D. Del. Apr. 29, 2021), and further lost its preliminary injunction motion on one of the patents asserted against CoreRx. D.I. 11-1, 103:12-24 ("And I'm denying it [Azurity's motion for a preliminary injunction] here because principally, plaintiffs have failed to show a likelihood of success on the merits."). To the extent that federal patent law is implicated in this dispute, it has spoken in *favor* of Bionpharma being permitted to sell its product. Indeed, patent-like protection can be provided *only* by federal patent law, and state law may not impose an intellectual property regime that would interfere with sale of products that are not prohibited under federal patent law. *Bonito Boats, Inc. v. Thunder Craft Boats*, *Inc*., 489 U.S. 141, 152 (1989) ("[O]our past decisions have made clear that state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws. The tension between the desire to freely exploit the full potential of our inventive resources and the need to create an incentive to deploy those resources is constant. Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess.); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 232-33 (1964) (state

unfair competition law cannot prevent sale of product based on copying in absence of a valid patent protecting the source product).

As the Court held, *Lear v. Adkins* does not stand for the broad proposition urged by CoreRx. In *Lear*, the Supreme Court considered whether the common-law doctrine of licensee estoppel adhered to by some state courts—under which the licensee of a patent was estopped simply by virtue of having taken a license from contesting the patent's validity in a suit for royalties under the license agreement—should be abrogated. D.I. 50 at 18-19 (citing *Lear* 395 U.S. at 656). The Court did not err in concluding that nothing in *Lear* held that contracts to sell products that *allegedly* infringe a patent are presumptively void, the interpretation CoreRx seeks here. D.I. 50 at 19-20.

CoreRx's argument that the weight of authority supports its position is incorrect. The cases it cites for sweeping proposition that allegations of infringement nullify contracts do nothing of the sort. *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), held that a license agreement requiring payment of royalties under a patent *after the patent expired* was unenforceable. *Id.* at 33-34. *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249 (1945), held that the assignor of a patent was not estopped from making use of an earlier, expired patent. *Id.* at 257-58. *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257 (1979), held that a license agreement to a pending patent application was not rendered unenforceable despite a patent not issuing, because the parties had contemplated and provided for that possibility in the agreement. *Id.* at 266.

Both *Idaho Potato Comm'n v. M & M Produce Farm & Sales*, 335 F.3d 130, 139 (2d Cir. 2003), and *Rates Tech. Inc. v. Speakeasy, Inc.*, 685 F.3d 163, 174 (2d Cir. 2012), simply applied *Lear's* holding abrogating the principle of licensee estoppel to similarly hold that no-challenge provisions in contracts were unenforceable. *Alexsam, Inc. v. Mastercard Int'l Inc.*, No.

15CV2799ILGSMG, 2018 WL 7063137 (E.D.N.Y. Oct. 16, 2018), held that a forum selection clause did not bar a patent licensee from challenging the validity of its licensed patents before the PTO's Patent Trial and Appeal Board. *Id.* at *5-7. Finally, *Canon Inc. v. Tesseron Ltd.*, 115 F. Supp. 3d 391 (S.D.N.Y. 2015), applied *Lear* to hold that punitive contract clauses triggered by a licensee's challenge to the validity of the licensed patents were unenforceable, as essentially equivalent to an unenforceable covenant not to challenge validity at all. *Id.* at 395-96. None of these cases support CoreRx's argument.

Even if the Product did infringe valid claims of the Azurity patents—and CoreRx presents no evidence that it does—CoreRx's performance would not be "illegal" as that term is used in contract law. Patent infringement is a civil tort, *Wordtech Sys., Inc v. Integrated Networks Sols., Inc.*, 609 F.3d 1308, 1313 (Fed. Cir. 2010), not a criminal or *malum in se* act that would void a contract for illegality. *Benjamin v Koeppel*, 85 N.Y.2d 549, 553 (1995); *Lloyd Cap. Corp. v Pat Henchar, Inc.*, 80 N.Y.2d 124, 127 (1992). Under CoreRx's theory, a contract for sale of any product that carried the mere possibility, proven or otherwise, of causing a third-party injury from patent infringement to products liability would be void on its face, which is an untenable result.

CoreRx's cited cases regarding illegality again fail to support its position. *Village Taxi Corp. v. Beltre*, 933 N.Y.S.2d 694, 700 (2d Dep't 2011), voided the private sale of taxicab licenses where the parties sought to avoid completing required license applications with the issuing authority, bypassing background checks and other pertinent regulations. *24/7 Recs., Inc. v. Sony Music Entm't, Co.*, No. 03 CIV. 3204(MGC), 2004 WL 2093132, at *5 (S.D.N.Y. Sept. 20, 2004), concerned a contract for distribution of unlicensed, copyrighted materials, and the district court specifically noted that the contract at issue was not unenforceable as-written, or

even when the possibility of non-infringing use existed (due to the Copyright Act's compulsory licensing provisions), but only upon the incurable failure of a party to secure a license after the passing of strict time bars. And *Anabas Exp. Ltd. v. Alper Indus. Inc.*, 603 F. Supp. 1275, 1276 (S.D.N.Y. 1985), rested on the fact that neither party disputed that the contract expressly required violation of New York law governing distribution of depictions of individuals without consent. None of CoreRx's cases voided a contract because of a mere *possibility* or *allegation* of third-party injury.

CoreRx has no likelihood of success on appeal of either its preemption or illegality claims. The required condition precedent to underpin any such finding—that the Product has been found to infringe a valid and enforceable patent—is entirely absent, with only allegation and conjecture in its place. Without this fundamental assumption, CoreRx's theories fail.

2. The Court's finding that Bionpharma made a showing of irreparable harm was not clearly erroneous

CoreRx errs by faulting the Court for crediting Bionpharma's evidence, by way of testimony of its CEO Venkat Krishnan, that Bionpharma will be irreparably harmed in the absence of an injunction. D.I. 83 at 12-13.

First, the Court's fact-finding here will remain undisturbed on appeal, as it was not in clear error. *Zervos*, 252 F.3d at 168. CoreRx's criticism of Bionpharma's evidence as "conclusory" falls flat. Mr. Krishnan explained the importance of the Product to Bionpharma's portfolio, to the positive impact on Bionpharma's reputation of achieving the first generic approval and launching the Product, to the fact that Bionpharma is a party to numerous distribution agreements of its own for which it will soon find itself in breach, to the impact that a sudden inability to supply would have on Bionpharma's reputation as a reliable vendor of generic drugs, and to the fact that Bionpharma has already lost business opportunities as a result

of CoreRx's conduct, including being forced to turn down a contract for the sale of a significant quantity of the Product. D.I. 14 ¶¶ 24-34. This testimony is not conclusory, is unrebutted, and the Court's decision to credit it is not clearly erroneous.[2]

CoreRx asserts, without support, a black-letter rule that reputational harm may only be found where the movant's business is at risk by virtue of the other party's conduct. D.I. 83 at 11-12. No such rule exists. Rather, a company's "loss of reputation, good will, and business opportunities" from a breach of contract can constitute irreparable harm. *Register.com, Inc. v. Verio, Inc.*, 356 F.3d 393, 404 (2d Cir. 2004); *CRP/Extell Parcel I, L.P. v. Cuomo*, 394 F. App'x 779, 781 (2d Cir. 2010) ("we have upheld an award of injunctive relief where a movant claimed money damages that were hard to measure plus irreparable harm, including loss of reputation, goodwill and business opportunities.); s*ee also Reuters Ltd. v. United Press Int'l*, 903 F.2d 904, 909 (2d Cir. 1990) ("In cases where a preliminary injunction has issued to prevent a product source from suspending delivery to a distributor, the irreparable harm has often consisted of the loss of customers and the competitive disadvantage that resulted from a distributor's inability to supply its customers with the terminated product."); *John B. Hull, Inc. v. Waterbury Petroleum Prods., Inc.*, 588 F.2d 24, 29 (2d Cir.1978) (irreparable injury shown when "plaintiff is deprived totally of the opportunity to sell an entire line of merchandise and may incur injury to its goodwill and reputation 'as a dependable distributor'"). The Court correctly found that Bionpharma made such a showing. D.I. 50 at 13-14.

[2] CoreRx stipulated with Bionpharma that the preliminary injunction would be decided on the papers (no live testimony). D.I. 25. If it had concerns about Mr. Krishnan's declaration, it did not have to so-stipulate.

CoreRx incorrectly tries to distinguish the ample authority relied upon by the Court by alleging that in all such cases, the product to be supplied was the only product in the movant's line of business. Such is not the case. In *Rex Medical L.P. v. Angiotech Pharmaceuticals (US), Inc.*, 754 F. Supp. 2d 616 (S.D.N.Y. 2010), the improperly withheld product was a majority of the movant's business, but not the only product. *Id.* at 622-23. In *Eastman Kodak Co. v. Collins Ink Corp.*, 821 F. Supp. 2d 582 (W.D.N.Y. 2011), there was simply no allegation that the ink supplied by the defendant constituted the entirety of Kodak's business, and common sense (in the case of a large company like Kodak) makes that possibility very unlikely. Ultimately, the common fact underlying the findings of irreparable harm in the cases relied upon by the Court is that the movant would suffer reputational damage and loss of business opportunity as a result of the nature of the ***product***, not the nature of the movant's business. *John B. Hull*, 588 F.2d at 29 (irreparable injury shown when "plaintiff is deprived totally of the opportunity to sell an entire line of merchandise and may incur injury to its goodwill and reputation 'as a dependable distributor'"); *Eastman Kodak*, 821 F. Supp. 2d at 588–89 ("An inability on Kodak's part to provide such ink to its customers therefore threatens to cost it customer goodwill, the loss of which cannot easily be quantified or reduced to a dollar amount."); *Reuters*, 903 F.2d at 907–08 ("terminating the delivery of a unique product to a distributor whose customers expect and rely on the distributor for a continuous supply of that product almost inevitably creates irreparable damage to the good will of the distributor"). CoreRx's attempt to create a distinction where none exists fall flat, as further evidenced by its inability to identify a single case where a substantial showing of reputational harm and loss of opportunity was disqualified as part of irreparable injury because the loss of a product was not a sufficiently large percent of the movant's portfolio.

Finally, CoreRx alleges that the Court of Appeals will find that the limitation of liability clause prohibits injunctive relief. This is contrary to the text of the Agreement itself, and the Court's reasoning that the provision's exclusion of certain categories of damage give rise to the implication that non-recited categories are not likewise restricted. *Quadrant Structured Prod. Co. v. Vertin*, 23 N.Y.3d 549, 560 (2014) ("Even where there is ambiguity, if parties to a contract omit terms—particularly, terms that are readily found in other, similar contracts—the inescapable conclusion is that the parties intended the omission. The maxim *expressio unius est exclusio alterius*, as used in the interpretation of contracts, supports precisely this conclusion"); *see also In re Ore Cargo, Inc.*, 544 F.2d 80, 82 (2d Cir. 1976) (where sophisticated drafter omits a term, *expressio unius* precludes the court from implying it from the general language of the agreement). Moreover, the Court held that the parties' limitation of liability might cut the other way in justifying the need for injunctive relief, because "absent preliminary relief, [Bionpharma's] ability to be made whole after a wrongful [breach] would be seriously jeopardized." D.I. 50 at 16, *citing Rockwood Pigments NA, Inc. v. Elementis Chromium LP*, 2 N.Y.S.3d 94, 97 (1st Dep't 2015).

The Court's conclusion that Bionpharma will suffer irreparable harm is based on detailed and unrebutted factual testimony, and is consistent with controlling or persuasive precedent.

B. CoreRx's purported injury in the absence of a stay is not actual, imminent, or irreparable

Establishing irreparable injury in the absence of a stay requires the movant to show that the claimed injury is actual and imminent, not remote or speculative. *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 884 F. Supp. 2d 108, 123 (S.D.N.Y. 2012). Here, CoreRx's claimed injury is its potential liability to its sister company Azurity. To the extent such liability arises from the CoreRx/Azurity settlement agreement (D.I. 54-1), it is an injury of CoreRx's own

making. And to the extent it arises from a potential claim for patent infringement, it is hypothetical and remote, and undermined by the Delaware court's denial of Azurity's request to enjoin Bionpharma's sale of Product.

Any liability by CoreRx to Azurity for patent infringement claim follows only from a chain of speculative future events. In order for CoreRx's alleged harm to come to pass:

- Azurity must sue CoreRx for patent infringement (no case is pending);
- the patents must be adjudged valid and infringed (no such judgment exists, and Azurity's motion for a preliminary injunction against Bionpharma was denied);
- all of CoreRx's various defenses to the hypothetical claim for patent infringement must fail;
- lost-profits damages must be assessed instead of reasonable royalty;
- a finding of willful infringement must be made;
- enhanced damages must be awarded by the trial judge;
- Azurity must pursue and collect damages from CoreRx instead of collecting damages from Bionpharma from the case that is already pending in Delaware, which would surely be resolved first; and
- Bionpharma either has no obligation to indemnify CoreRx under the parties' supply agreement, or has an obligation to indemnify but fails to do so.

CoreRx's alleged harms presuppose the entire course and outcome of litigation that has not even been initiated, and includes multiple unlikely and near-unsupportable assumptions. *Chevron Corp. v. Donziger*, 37 F. Supp. 3d 653, 659 (S.D.N.Y. 2014) (where alleged injury is contingent on outcome of litigation, there is no immediate injury).

Furthermore, the Court has already considered the grounds upon which CoreRx pleads that it will be irreparably harmed, *i.e.*, the alleged inability of Bionpharma to satisfy damages. As the Court found, CoreRx's allegations that Bionpharma lacks the financial capital to reimburse CoreRx for any meaningful share of a damages award were not compelling. D.I. 50 at

24. Additionally, CoreRx was (or should have been) aware that contracting with Bionpharma to manufacture a generic version of Epaned might expose it to potential liability. As such, its current "doubts" about Bionpharma's ability to pay or alleged fears of subsequent litigation by Azurity do not constitute immediate and irreparable harm. *Id.*

Of course, "quantifiable money damages cannot be deemed irreparable harm." *Harris v. Butler*, 961 F. Supp. 61, 63 (S.D.N.Y. 1997). CoreRx's alleged harms would be a money judgment in favor of its sister company Azurity, which is the epitome of a quantified sum. At oral argument, CoreRx also quantified its alleged potential exposure (albeit off-the-cuff and inaccurately). Tr. at 18:17-24 ("THE COURT: Would damages be for producing one bottle? … MR. FEDOWITZ: Your Honor, I could do the calculation real quick. For 18,000 bottles, that would equate to about nine million dollars going at five hundred dollars a bottle, which is what Azurity sells it for."). Although CoreRx's counsel did not have it at the time, Azurity has since provided a different (lower) per-bottle price estimate. D.I. 68 at ¶¶ 13-14 (providing estimate of gross profit, so net profit would presumably be somewhat less).

Finally, although CoreRx could have and did not argue it before, it now alleges for the first time that it could potentially be forced to declare bankruptcy; proverbially turn out the lights and lock the gates; and lay off its entire workforce. D.I. 83 at 15; D.I. 85 ¶¶ 15-18. This should be rejected as sophistry. First, a going concern is able to reorganize in bankruptcy under Chapter 11, and would not be forced into a "full shutdown of operations" that would destroy its value. Second, a judgment held by Azurity against its sister company CoreRx, both of which are subsidiaries of the venture capital company NovaQuest, might result in a reallocation of executive bonuses or internal ledger transactions, but it would not plausibly result in the destruction of an otherwise viable business.

C. A stay would substantially injure Bionpharma

CoreRx's argument that Bionpharma will suffer no material harm from a stay is, of course, contrary to the Court's finding that Bionpharma would suffer from irreparable harm in the absence of a preliminary injunction. D.I. 50 at 13-17 (addressing Bionpharma's showing of irreparable harm, CoreRx's counter-arguments, and concluding that "Bionpharma has made a strong showing of irreparable harm in the absence of an injunction.").

Because they are not clearly erroneous, the Court's factual determinations are not subject to a meritorious challenge on appeal. *Zervos*, 252 F.3d at 174 (affirming denial of motion for preliminary injunction under abuse of discretion standard, holding it "was not based on an error of law or on a clearly erroneous finding of fact"). Here, CoreRx's argument that Bionpharma would suffer only quantifiable money damages is substantially confined to attorney argument without supporting evidence. However, even if CoreRx *had* introduced evidence to counter Bionpharma's showing of irreparable injury established through the declaration of its CEO Venkat Krishnan (D.I. 14), the Court's factual findings would be practically unassailable on appeal under the clearly erroneous standard of review. *Anderson v. City of Bessemer City*, 470 U.S. 564, 573-74 (1985) ("Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous. This is so even when the district court's findings do not rest on credibility determinations, but are based instead on physical or documentary evidence or inferences from other facts."); *see also Zervos*, 252 F.3d at 171-72 (clearly erroneous standard applies even if district court's factual determinations were not based on live testimony).

Further, a stay that causes Bionpharma to exhaust its inventory and prevents it from continuing to accept and fill orders would present Azurity with the opportunity to capture

Bionpharma's market share by launching its own "authorized generic" of Epaned.[3] At oral argument of Azurity's motion for a preliminary injunction against a second generic filer (Annora) in Delaware, Azurity told the court that it was "poised to launch the authorized generic because we have notice that Annora wishes to launch at risk." Exhibit 1 at 28:6-13.[4] As the Court knows, the Delaware court denied Azurity's motion for a preliminary injunction against Annora, *id.* at 55-74, and Annora may be able to launch its generic as soon as February 14 (the day after Bionpharma's first-filer exclusivity expires). If Bionpharma is deprived of supply, or constrained from accepting firm orders from its customers because of the delays or uncertainty caused by a stay, Azurity (and Annora) would have the opportunity to capture Bionpharma's business.

D. The public interest favors denial of a stay

The public interest weighs heavily against a stay. Bionpharma's product is currently available to pediatric consumers, but that situation cannot be maintained absent enforcement of the injunction. D.I. 14 ¶ 25; D.I. 41 ¶ 3 ("Bionpharma will exhaust its inventory of Product before this process is completed, and will then be unable to supply its customers."). The Court's finding that maintaining Bionpharma's product in the marketplace serves the public interest rests on sound reasoning and supporting facts, and aligns with the Delaware court's same finding on this issue in Bionpharma's favor. D.I. 11-1 at 110:1-19.

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[3] An authorized generic is a product manufactured by the brand company but without the branded product's trademarks. It is sold as a generic, typically at generic pricing. *See Sanofi-Aventis v. Apotex Inc*., 659 F.3d 1171, 1174-75 (Fed. Cir. 2011).

[4] *See* Declaration of Charles A. Weiss in Opposition to Defendant CoreRx's Motion (D.I. 82) for Stay of Injunction Pending Appeal, filed concurrently herewith.

CoreRx again argues that generalized and non-specific public interest in "promoting and rewarding innovation" is more important to the public, but that is not even applicable here. As the Court noted (and which is not disputed), "no court has ever found Bionpharma to be in breach of the federal patent laws." D.I. 50 at 25. The public's interest in the federal patent laws is not to bar competition absent a judgment or concession in favor of a patent owner, thus extending the patent monopoly to apply to mere accusations of infringement. Here, Azurity's alleged innovation has resulted in patents, on which it has sued Bionpharma in Delaware. The fact that its enforcement has been unsuccessful to date speaks to the weakness of its patents, and the public interest is not served by giving them strength via this case that they have not obtained in the infringement cases.

II. CORERX'S BELATED REQUEST FOR SECURITY SHOULD BE DENIED

Having failed to request any security in its opposition to the preliminary injunction motion, or when submitting its proposed counter-order granting the injunction, CoreRx now belatedly seeks an order compelling Bionpharma to post an $88 million bond. Its late-breaking request has been waived. This is particularly so, given that there is no proof in the record to support a bond in the requested amount of $88 million. As discussed below, if a bond is to be required at this stage, Bionpharma submits that a bond in the amount of $200,000 would be fitting and proper, in order to secure any losses that CoreRx may sustain under the terms of the parties' Master Supply Agreement in the event that it supplies Product as ordered and Bionpharma fails to pay for it.

A. CoreRx has waived any entitlement to a bond by not timely requesting one, and by submitting a form of order that did not require a bond

The burden is on the party seeking security to establish a rational basis for the amount of the proposed bond. *Int'l Equity Invs., Inc. v. Opportunity Equity Partners Ltd.*, 441 F. Supp. 2d

552, 566 (S.D.N.Y. 2006), *aff'd*, 246 F. App'x 73 (2d Cir. 2007). CoreRx failed to establish the basis for the proposed bond in a timely manner; indeed, it failed to even request a bond in the first instance. It further failed to include a request for a bond in its proposed injunction order. D.I. 59. Where no request for a bond has been made, and neither party addressed the issue of a bond in the course of the preliminary injunction motion practice, a court may decline to require one. *Vozzolo v. Air Canada*, No. 20-CV-03503 (PMH), 2021 WL 5113387, at *8 n.6 (S.D.N.Y. Nov. 3, 2021). CoreRx has waived its arguments for a bond, and its application should be denied.

B. The purported damages for which CoreRx seeks security are speculative and remote

"It is well-settled that a district court has 'wide discretion in the matter of security and it has been held proper for the court to require no bond where there has been no proof of likelihood of harm.'" *New York City Triathlon, LLC v. NYC Triathlon Club, Inc.*, 704 F. Supp. 2d 305, 345 (S.D.N.Y.2010) (*quoting Doctor's Assocs., Inc. v. Stuart*, 85 F.3d 975, 985 (2d Cir.1996)); *see also Clarkson Co. v. Shaheen*, 544 F.2d 624, 632 (2d Cir.1976). "The purpose of [Rule 65(c)] is to enable a restrained . . . party to secure indemnification for the costs . . . and pecuniary injury that may accrue during the period in which a wrongfully issued equitable order remains in effect." 11A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 2954 (2d ed. 1995). As the Second Circuit explains, "The injunction bond is designed 'to cover any damages that might result if it were later determined that [the applicant] was not entitled to an injunction.'" *Blumenthal v. Merrill Lynch, Pierce, Fenner & Smith*, 910 F.2d 1049, 1055 (2d Cir. 1990) (*quoting Com. Tankers Corp. v. Nat'l Mar. Union*, 553 F.2d 793, 800 (2d Cir.1977)). A court "is not required to order security in respect of claimed economic damages that are no more than speculative." *Int'l Equity Invs*., 441 F. Supp. 2d at 556.

Here, CoreRx will suffer no direct pecuniary injury that may accrue from the entry of the injunction. "[B]eing forced to comply with contractual obligations that a party voluntarily entered into is simply not the sort of damage that is compensable at law." *Rex Med.*, 754 F. Supp. 2d at 627; *Eastman Kodak*, 821 F. Supp. 2d at 590 ("All that this injunction does is require Collins to continue to perform under the contract, as it has been doing for years. That hardly constitutes a cognizable harm to Collins."). Simply put, the injunction requires CoreRx to manufacture the Product, as the Agreement requires, and Bionpharma will pay CoreRx for that Product, again as the Agreement requires. There is no possibility of direct, immediate, and certain injury to CoreRx if the injunction turns out to have been erroneously issued.

In any event, CoreRx's request for security for the speculative damages that it claims will be sustained as a result of a patent infringement lawsuit, twice dismissed and that has not yet been asserted for the third time, is not sustainable as a matter of law. *See Medafrica Line, S.P.A. v. Am. W. Afr. Freight Conf.*, 654 F. Supp. 155, 156 (S.D.N.Y. 1987) (The only damages recoverable from an injunction bond are those arising from the operation of the injunction itself and not from damages occasioned by the suit independently of the injunction); *see also Lever Bros. Co. v. Int'l Chemical Workers Union*, 554 F.2d 115, 120 (4th Cir. 1976) (The injunction must be the proximate cause of the damages); *CVI/Beta Ventures, Inc. v. Custom Optical Frames, Inc.*, 893 F. Supp. 508, 525 (D. Md. 1995), *aff'd*, 92 F.3d 1203 (Fed. Cir. 1996) ("Moreover, damages claimed under an injunction bond must arise from the operation of the injunction, not from damages occasioned by the suit independently of the injunction.").

Finally, when deciding whether to require security, a court may properly consider the likelihood that on reconsideration or on appeal, the court will find that the injunction should not have issued, and the greater a plaintiff's likelihood of success on the merits, the lower the

probability that an injunction in the plaintiff's favor will later be determined to have been issued in error. *Eastman Kodak*, 821 F. Supp. 2d at 590. A strong likelihood that a plaintiff will succeed on the merits counsels in favor in declining to require a bond. *Id.*; *New York City Triathlon*, 704 F. Supp. 2d at 345 ("Defendant has not demonstrated it will likely suffer any harm absent the posting of a bond, and the likelihood of success on the merits is overwhelming. Therefore, the Court declines to require one."). As discussed at length in Bionpharma's moving papers and above, Bionpharma's likelihood of success on the merits is high. CoreRx's only defense to its breach is its novel, sweeping legal theory that, once a party is merely accused of infringing a patent, its contracts to make, use, or sell such an accused product are null and void as preempted and illegal. For this additional reason, the Court should decline to require a bond.

C. If the Court grants CoreRx's request for security, it should be for $200,000

The basis for calculating a bond value is the direct and immediate damage that would result to a wrongfully enjoined party, not remote or speculative amounts. *Int'l Equity Invs.*, 441 F. Supp. 2d at 566 ("In fixing the amount of security required, a court is not required to order security in respect of claimed economic damages that are no more than speculative."). As discussed above, CoreRx's proposed damages are entirely speculative, which even comes through in part in its brief. D.I. 83 at 20 ("should the Preliminary Injunction not be stayed, CoreRx *could* be subject to liability to Azurity for patent infringement") (emphasis added).

While Bionpharma contends that no bond need be required, at most a bond should be in the amount of $200,000. This is calculated based on the quantity of bottles to be delivered times the transfer price sought by CoreRx. This amounts to modestly less than $200,000, which can be rounded up to $200,000.

III. CORERX SHOULD BE REQUIRED TO POST SECURITY IF THE COURT GRANTS A STAY

Security may be required to secure a stay pending appeal. Fed. R. Civ. P. 62(d) ("While an appeal is pending from an interlocutory order or final judgment that grants … an injunction, the court may suspend … an injunction on terms for bond or other terms that secure the opposing party's rights"). Here, CoreRx alleges that its potential exposure for a wrongfully entered injunction would amount to $88,000,000. That amount is frankly absurd, but if CoreRx is serious about it, it cannot dispute that a bond in favor or Bionpharma in the modest amount of 10% of that amount would be the minimum necessary to protect Bionpharma from an erroneously granted stay that is later vacated.

IV. THE COURT SHOULD DENY CORERX'S REQUEST FOR A STAY TO SEEK RELIEF FROM THE SECOND CIRCUIT

The decision of whether a stay is warranted under these circumstances is not close. CoreRx's inability to make even a minimal showing that it may be granted a stay warrants denial of any relief whatsoever. *Everspeed Enters. Ltd. Pte. Ltd. v. Skaarup Fortune Shipping Ltd.*, No. 09 CIV. 1319 (LBS), 2010 WL 1541420, at *2 (S.D.N.Y. Apr. 15, 2010) ("[b]ecause Plaintiff has not made even the minimal showing … Plaintiff's request for a temporary stay while it seeks a stay from the Court of Appeals is denied."). Additionally, CoreRx's lack of cognizable harm from the grant of the injunction further counsels against the entry of a stay. *Marshak v. Reed*, 199 F.R.D. 110, 111 (E.D.N.Y. 2001) ("I also decline to issue a temporary stay while Reed seeks a stay pending appeal from the Second Circuit. There is no showing that Reed will suffer harm in the interim before the Second Circuit can consider his application ….").

As set forth on page 2, *supra*, CoreRx has work to do in order to meet the delivery deadlines of the preliminary injunction. D.I. 79 ¶ 2. It can and should keep that work moving along, to make sure that the deadlines are not missed if it ultimately fails to obtain a stay. A

temporary stay that CoreRx could rely on to stop its work, and use an excuse for the missed deadlines, is unwaranted and would prejudice Bionpharma. CoreRx's request should be denied.

CONCLUSION

CoreRx's motion should be denied in its entirety.

Respectfully submitted,

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Bionpharma Inc.

DATED: February 11, 2022
New York, New York

By: */s/ Charles A. Weiss*
CHARLES A. WEISS

CERTIFICATE OF COMPLIANCE

I certify that the accompanying Brief in Opposition to Defendant CoreRx's Motion (D.I. 82) for Stay of Injunction Pending Appeal contains 6,648 words, excluding the parts of the document that are exempted. This certificate was prepared in reliance on the word-count function of the word processing system (Microsoft Word) used to prepare the brief.

DATED: February 11, 2022
New York, New York

/s/Charles A. Weiss
CHARLES A. WEISS